

REMARKS

This paper is submitted in response to the office action the Office mailed on January 12, 2006.

The amendments of paragraph 1 changes the designation of this application from a divisional to a continuation. The amendment of specification paragraph 697 beginning at page 239 replaces the diagrams (at pages 241-244) in the specification with tables containing the data originally present in the diagrams. Amendments of other paragraphs in the specification correct typographical errors. These amendments introduce no new matter.

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Nonstatutory double patenting

The Office provisionally rejected claims 32-37 under the judicially created obviousness-type double patenting over claims 1-10, 15-19, 22 and 23 of copending application No. 10/877,911. Applicants respectfully traverse the rejection and note that this rejection is not procedurally ripe for consideration. Because of this, Applicants request the Office to hold this provisional rejection in abeyance until patentable subject matter is identified in either this application or in copending application No. 10/877,911. The filing of a terminal disclaimer at this time is premature. Once patentable subject matter is identified, Applicants can properly address this issue, the terms of which will depend on the scope of allowable subject matter in either of these applications.

The Office provisionally rejected claims 32-34 under the judicially created obviousness-type double patenting over claim 1 of copending application No. 10/749,981. Applicants respectfully traverse the rejection because application No. 10/749,981 is not commonly owned and it has different priority dates from the present application. The judicially created law of obviousness-type double patenting was developed to cover the situation where patents or applications are not citable as a reference against each other and therefore can not be examined for compliance with the rule that only one patent is available per invention. Double patenting is thus applied when neither patent is prior art against the other, usually because they have a common priority date. *Eli Lilly and Co. v. Barr*

Laboratories Inc. et al., 251 F.3d 955, 58 U.S.P.Q. 2D 1865 (Fed. Cir. 2001). In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection.

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35 U.S.C. § 112, second paragraph

The Office rejected claims 32-37 as indefinite for lack of antecedent basis for R¹³ in claim 32 and lack of antecedent basis in claim 34 for R⁹ substituents – O- and -NH-. Applicants have amended claims 32 and 34 and the rejection should be moot.

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The Office objected to claim 36 as improperly depending on claim 35. Applicants have amended claim 35 to provide a basis for the compounds in amended claim 36 and the rejection should be moot.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejections.

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35 U.S.C. § 102(b)

The Office rejected claims 32-34 as allegedly anticipated by U.S. patent 6,432,940 (the '940 patent). Applicants respectfully traverse the rejection.

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In casting the rejection, the Office alleged that the compound the '940 patent discloses, androst-5-ene-3β,17β-diol, anticipates claims 32-34 because they recite androst-5-ene-3β,17β-diol. Since claims 32-34 do not recite any compound having a hydroxyl group in the β-configuration at the 3-position, the '940 patent cannot anticipate any of the claimed subject matter. Applicants request reconsideration and withdrawal of the rejection.

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35 U.S.C. § 103(a)

The Office rejected claims 32-34 and 36 as allegedly obvious over U.S. patent 6,432,940 (the '940 patent). Applicants respectfully traverse the rejection.

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To establish a case of prima facie obviousness under § 103, consideration of whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and whether the prior art would also have revealed that in so

making or carrying out, those of ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991), *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). The court has observed that obviousness under 35 U.S.C. 103(a) requires that both "the suggestion and

5 the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." citing *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). *Velander v. Garner*, 348 F.3d 1359; 2003 U.S. App. LEXIS 22717; 68 USPQ2D (BNA) 1769 (Fed. Cir. 2003).

10 In casting the rejection, the Office alleged that the compound the '940 patent discloses, androst-5-ene-3 β ,17 β -diol, renders claims 32-34 and 36 unpatentable because they recite the 3 α -isomer of androst-5-ene-3 β ,17 β -diol and this subject matter is obvious based on the holding in *In re Norris*, 179 F.2d 970, 84 U.S.P.Q. 458 (C.C.P.A. 1970). Applicants have amended claims 32, 35

15 and 36 so that androst-5-ene compounds are no longer recited. The '940 patent does not teach or suggest the presently claimed subject matter, nor does it provide a reasonable expectation of success for the use of the presently claimed compounds. *In re Vaeck* and *Velander v. Garner*, both cited above. The compounds in the amended claims are not just 3 α -isomers of androst-5-ene-

20 3 β ,17 β -diol, since the claims recite additional structure differences.

 In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection.

Respectfully submitted,

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